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October 21, 2016

Vindell Washington, MD
Office of the National Coordinator for Health Information
Technology
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
RE: *Comments on the Draft 2017 Interoperability Standards Advisory*
<Submitted Electronically>

Dear Dr. Washington,

On behalf of Cerner, I am writing to provide input to the draft 2017 Interoperability Standards Advisory (2017 ISA). We appreciate the efforts of you and your team to improve on the ISA to help make this a valuable document for the industry to the best available interoperability standards and implementation specifications.

Cerner associates have participated in the collaborative efforts led by the Electronic Health Record Association (EHRA) as well as with HL7 to provide input to the draft 2017 ISA. We largely support and endorse those comments and refer to their response for more detailed considerations; however, we are also responding individually to urge you and your team to consider the following general concerns.

We appreciate the enhancements made to the interoperability characteristics, links to the Interoperability Proving Ground, and continued emphasis on including implementation guides rather than foundational standards.

- There are a number of audiences that could benefit from the ISA, but navigating the volume of use cases and standards/implementation guides can be challenging. The introduction of a link to the Interoperability Proving Ground would be even more helpful if one can navigate from the project on the Interoperability Proving Ground to the associated interoperability need and specifically highlights the standards/implementation guides being applied.

Additionally, with the move to a web based publication, introduction of filtering capabilities on the interoperability characteristics may further assist in stakeholders to find the interoperability needs where standards/implementation guides have a certain threshold or characteristic.

- We suggest that as part of the introduction to the ISA it is clarified to all readers that, just because a standard has been balloted in an approved process, does not mean that the standard is fit for purpose for any specific use case. We urge all standards to be tested in extensive pilot settings before any

consideration is given for requiring that standard in regulatory or otherwise binding contexts. We suggest that indications of the level of testing performed (connectathons, pilots, early rollout) be more clearly documented to further aid with this understanding.

- To help understand fit for purpose, various use cases and interoperability needs remain challenging to assess the appropriateness of the standards/implementation guide listed. We suggest that each interoperability need includes a brief paragraph of the intended purpose that is not readily derived from the title. As an example, the “Push Exchange” use case lists an interoperability need that uses “unsolicited” in the title. We believe that qualifier may not be needed, or an alternative interoperability need may be appropriate such as “solicited” push. Similarly, the Care Plan interoperability needs’ standards/implementation guides have limited applicability, but without a clarification beyond the interoperability title it is unclear whether the standards/implementation guides are appropriate or insufficient.
- We are concerned with the invitation to federal agencies in particular to consider the ISA first as they are establishing their initiatives involving HIT. While the document certainly serves a useful purpose to get acquainted with currently available standards/implementation guides in one place, as currently stated there is a risk of agencies selecting standards from the ISA that are not yet present in the certification edition or could conflict with selections made in the certification edition. We suggest to make more clear that the certification edition should be the first place to identify interoperability capabilities using specific standards/implementation guides and that agencies work with ONC to determine which standards/implementation guides should be included into the certification edition to promote HIT to support a common, basic set of interoperability capabilities.

This suggestion will also help clarify what the predictive value of the ISA is as without clarity on how/when standards/implementation guides may be included in a future certification edition the ISA will go largely unused. Larger organizations already active in standards/implementation guide development already have the wherewithal to have this inventory and access to all information, while smaller organizations have no further insight on where to focus their attention. Thus, the challenge remains that without regulatory pressure to adopt specific standards and implementation specifications as “minimum required” to support basic out-of-the-box interoperability, while leaving opportunity for advanced interoperability and innovation between tightly collaborating partners and networks without penalty, many organizations will not have the bandwidth or wherewithal to adopt the emerging and not yet mandatory standards and implementation specifications.

- For those not as familiar with the origins of the recommended standards and implementation guides, or with ongoing debates about the merits of competing standards, it would be very helpful to provide links to the fora where previous decisions/recommendations were made, e.g., HITSC meetings, Task Force

recommendations, etc. This is of particular interest for vocabularies and value sets, but would be helpful for all other standards and implementation guides as well. We were disappointed to see a number of those references dropped.

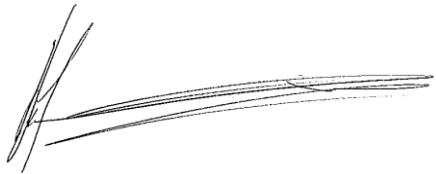
- We are concerned that the moment the ISA is published it is immediately out-of-date. Rather than pursuing an annual update cycle we suggest that ongoing updates can be applied having a continuous dialog opportunity to provide input and feedback on proposed updates. As an example, FHIR is rapidly maturing with implementation guides and adopt levels increasing. Particularly for those interested in emerging standards more frequent updates would be helpful. Using the web based publication approach can facilitate such a strategy.

Careful curation will be important if a wiki-like approach is adopted to ensure that accurate information is displayed, and to avoid “flame-wars” among standards partisans. The contributors to the ISA need not be limited to ONC staff, but could be extended to SDO or other qualified experts. It might be possible to solicit updates via the ISA web page itself, and then let ONC staff vet the additions and approve the suggestions that are contributory.

The challenges notwithstanding, we will continue to work ONC and various industry stakeholders to find the right constructs that can provide the necessary insight into the state of interoperability, establish a nationally endorsed set of standards and implementation specifications, and generally advance the level of interoperability necessary to enable full access to the electronic medical record for patients, providers, and other stakeholders to ensure the right data is available to the right person at the right time.

Please do not hesitate to contact me if we can be of further assistance.

Sincerely,



Hans J. Buitendijk, M.Sc., FHL7
Senior Strategist